CLAIMS:

Claims 1-3 (Cancelled)

4. (Currently Amended) A method of determining preferred targets for subject compliance during a current clinical trial, comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state, and wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or week, the amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial;

generating at least one preferred compliance threshold for ~~the~~ use during the current clinical trial by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data from the previous clinical trial; and

obtaining subject compliance information from a subject participating in said ~~during the~~ current clinical trial comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information; and

comparing the subject compliance information to the at least one preferred compliance threshold to determine if action is needed, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to

remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

5. (Canceled)

6. (Previously Presented) The method of determining preferred targets for subject compliance of claim 4, further comprising the step of prompting action if the step of comparing indicates that action is needed.

7. (Canceled)

8. (Currently Amended) A method of monitoring subject compliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state;

generating at least one algorithm reflective of the historical subject compliance data by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information;

obtaining the subject compliance information from a subject participating in said ~~during the~~ current clinical trial, comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical

staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

9. (Currently Amended) The method of predicting subject noncompliance of claim 8, wherein said step of providing ~~includes~~ further comprises providing historical protocol data, wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or week, the amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial and wherein said step of generating further comprises quantitative analysis of the historical protocol data.

10. (Original) The method of determining subject compliance of claim 9, wherein the step of providing employs at least one database containing the historical protocol data.

11. (Canceled)

12. (Original) The method of determining subject compliance of claim 8, wherein the step of generating employs at least one of the group of multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees and regression trees.

13. (Original) The method of determining subject compliance of claim 8, wherein the step of providing employs at least one database containing the historical subject compliance data.

14. (Currently Amended) A method of determining subject compliance during a current clinical trial; comprising the steps of:

providing historical subject compliance data and historical protocol data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state, and wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or week, the amount of time

allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial;

generating a spectrum of compliance representative of the historical subject compliance data not compliant with the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

obtaining subject compliance information from a subject participating in said ~~during the~~ current clinical trial, comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

comparing the spectrum of compliance to the subject compliance information to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

15. (Canceled)

16. (Currently Amended) A method of predicting subject noncompliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of

completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule for use during the current clinical trial;

obtaining subject compliance information from a subject participating in said ~~during the~~ current clinical trial comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed.

17. (Currently Amended) The method of predicting subject noncompliance of claim 16, wherein said step of providing further comprises ~~includes~~ providing historical protocol data and wherein said step of generating further comprises ~~includes~~ quantitative analysis of the historical protocol data, wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or week, the amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial.

18. (Original) The method of determining subject noncompliance of claim 17, wherein the step of providing employs at least one database containing the historical protocol data.

19. (Canceled)

20. (Original) The method of predicting subject noncompliance of claim 16, further comprising the step of creating an evaluability database adapted to store data related to subject compliance.

21. (Previously Presented) The method of predicting subject noncompliance of claim 20, further comprising the step of providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database.

22. (Previously Presented) The method of predicting subject noncompliance of claim 20, wherein the evaluability database is tailored to a condition affecting the subject.

23. (Original) The method of determining subject noncompliance of claim 16, wherein the step of providing employs at least one database containing the historical subject compliance data.

24. (Currently Amended) A method of enhancing subject compliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state;

generating at least one algorithm by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for using during the current clinical trial;

obtaining subject compliance information from a subject participating in said current clinical trial; and

comparing the subject compliance information to the at least one decision rule on a portable electronic device or a computer to determine if affirmative action is warranted, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

25. (Currently Amended) The method of predicting subject noncompliance of claim 24, wherein said step of providing further comprises ~~includes~~ providing historical protocol data and wherein said step of generating further comprises ~~includes~~ quantitative analysis of the historical protocol data, wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or week, the amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial.

26. (Original) The method of enhancing subject compliance of claim 24, further comprising the step of prompting action if the step of comparing indicates that affirmative action is warranted.

27. (Original) The method of enhancing subject compliance of claim 24, wherein the affirmative action further comprises ~~includes~~ reducing a number of occurrences of the step of obtaining subject compliance information.

28. (Original) The method of enhancing subject compliance of claim 24, wherein the affirmative action further comprises ~~includes~~ increasing a number of occurrences of the step of obtaining subject compliance information.

29. (Original) The method of enhancing subject compliance of claim 24, wherein the affirmative action further comprises ~~includes~~ giving a reward.

30. (Original) The method of enhancing subject compliance of claim 24, wherein the step of obtaining comprises ~~includes~~ the use of a portable electronic device capable of displaying information and receiving and storing input from a user.

Claims 31-47 (Cancelled)

48. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state, and wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or

week, the amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial; and

generating at least one preferred compliance threshold for the use during a current clinical trial by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data from a previous clinical trial.

49. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state;

generating at least one algorithm reflective of the historical subject compliance data by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information during a current clinical trial;

obtaining the subject compliance information from a subject participating in said ~~during the~~ current clinical trial;

comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to remediate poor

compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

50. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data and historical protocol data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state, and wherein historical protocol data comprises a question posed to a subject, the frequency of prompting of a subject during the day or week, the amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial;

generating a spectrum of compliance representative of the historical subject compliance data not compliant with the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

obtaining subject compliance information from a subject participating in a ~~during a~~ current clinical trial;

comparing the spectrum of compliance to the subject compliance information to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing

compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

51. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule for use during a current clinical trial;

obtaining subject compliance information from a subject participating in said ~~during the~~ current clinical trial;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said

clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

52. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data from a previous clinical trial, wherein historical subject compliance data comprises, data on timeliness of a data entry, data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state;

generating at least one algorithm by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for use during a current clinical trial;

obtaining subject compliance information from a subject participating in said ~~during the~~ current clinical trial; and

comparing the subject compliance information to the at least one decision rule to determine if affirmative action is warranted, wherein said action comprises removing all or part of the data from said subject participating in said current clinical trial from data analysis, removing all or part of the data from said subject participating in said current clinical trial from a report, removing said subject participating in said current clinical trial from said current clinical trial, prompting said subject participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial, providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

53. (Cancelled)

54. (New) The method of claims 4, 8, 14, 16, or 24, wherein said historical subject compliance data further comprises data on whether a subject had a relationship with a doctor or other medical professional, data on a number or percent of prompts not replied to by a subject, data on a subject's sleep/wake cycle, data on whether a subject had a bowel movement, data on an amount of time a portable electronic device is in suspend mode, data on a subject's gender, or data on a subject's location.

55. (New) The computer readable medium of claims 48, 49, 50, 51, or 52, wherein said historical subject compliance data further comprises data on whether a subject had a relationship with a doctor or other medical professional, data on a number or percent of prompts not replied to by a subject, data on a subject's sleep/wake cycle, data on whether a subject had a bowel movement, data on an amount of time a portable electronic device is in suspend mode, data on a subject's gender, or data on a subject's location.

56. (New) The method of claims 4, 8, 14, 16, or 24, wherein said action further comprises decreasing said portable electronic device's prompt frequency, increasing said portable electronic device's prompt frequency, increasing the loudness of an audible prompt of said portable electronic device, or administering a reward to said subject participating in the current clinical.

57. (New) The computer readable medium of claims 48, 49, 50, 51, or 52, wherein said action further comprises decreasing said portable electronic device's prompt frequency, increasing said portable electronic device's prompt frequency, increasing the loudness of an audible prompt of said portable electronic device, or administering a reward to said subject participating in the current clinical.